M40036 V8

# Synovasure®
# Comprehensive Infection Panel
# Test Requisition

*** Indicates required field. Failure to provide information will delay results.**

**Place Test Sticker Provided in Kit Here**
***(stickers not intended for use on tubes)***

***For Physician Accounts Only***

## CD Laboratories Account

**Account Number***

**Ordering Provider*** (Physician accounts only)

**Provider NPI*** (Physician accounts only)

**Practice/Laboratory Name & Address***

**Phone***

**Fax***

**Email**

## Patient

**Name*** *(Last, First)*

**Date of Birth***

**Gender*** ☐ Male ☐ Female

**Patient Address***

**Phone**

## Specimen

**Specimen Obtained in*** ☐ Hospital ☐ ASC ☐ Clinic/Office

**Collection Date*** (mm/dd/yyyy) _____ / _____ / _____

**Aspiration Site***

| Knee | Hip | Other _____ |
|---|---|---|
| ☐ Right | ☐ Right | ☐ Right |
| ☐ Left | ☐ Left | ☐ Left |

## Patient Insurance

*Note: A front/back scan of insurance card(s) is also preferred*

**Insurance Type*** ☐ Medicare ☐ Commercial ☐ VA/Govt ☐ Medicaid ☐ Other

**Primary Insurer***

**Address***

**Member ID***

**Group ID***

**Name of Insured***

**Relationship to Patient*** ☐ Self ☐ Spouse ☐ Other _____

**Secondary Insurer** *(if applicable)*

**Member ID**

**Group ID**

## Diagnosis/ICD-10-CM Coding *(see reverse for example codes)*

**Primary Code***

**Secondary Code** *(if applicable)*

## REQUIRED Supporting Documentation*

*Please attach copies of the following medical records:*

- Relevant office visit notes regarding joint symptoms
- Diagnostic imaging reports
- Laboratory test results, including any prior synovial fluid analyses
- Surgical history and operative reports (primary and revision, if applicable)
- Any documentation supporting suspected joint infection or diagnostic concerns

☐ **Attached**

☐ **To be sent separately (Fax#: 240-902-3330)**

## Patient Acknowledgement

By signing this form, I hereby authorize Zimmer Biomet to furnish my designated insurance carrier with medical documentation and information on this form, if necessary, for reimbursement. I also authorize benefits to be payable to Zimmer Biomet. I understand that I am responsible for any amounts not paid by insurance for reasons including, but not limited to, non-covered, out-of-network, and non-authorized services. I permit a copy of this authorization to be used in place of the original.

**Signature*** **Date***

## Test Information – Comprehensive Panel

For test descriptions and diagnosis codes, please see the reverse of this form.

*See "Required Volume" for amount and tube type for each test option. Tubes are provided within the Synovasure Infection Specimen Transportation Kit.*

☐ **Synovasure® Comprehensive Periprosthetic Joint Infection (PJI) Test Panel with SynTuition®*** and **Culture****

*Includes: Synovasure Alpha Defensin ELISA, Synovial Fluid CRP, WBC Count w/ Differential, and RBC count

***Includes Aerobic and Anaerobic Culture*

***Required Volume**: 3.0mL (No Additive Tube), 3.0mL (No Additive Tube) & 0.5mL (EDTA tube)*

☐ **Add-on: Crystal Analysis** *(+0.5mL to EDTA tube)*

☐ **Synovasure® Comprehensive Native Septic Arthritis (NSA) Test Panel**

Includes: Synovasure Alpha Defensin for NSA (alpha defensin and lactate), WBC Count w/ Differential and RBC count, Culture (Aerobic and Anaerobic), and Crystal Analysis

***Required Volume**: 3.0mL (No Additive Tube), 3.0mL (No Additive Tube) & 1.0mL (EDTA tube)*

## Test Information – Individual Tests *(select only if Comprehensive Panel is NOT desired)*

☐ **Synovasure® Alpha Defensin for PJI**

***Required Volume**: 0.5mL*

**Exclusively Serviced by:**
CD Laboratories, Inc. (CLIA Registration #21D0216863) | 810 Gleneagles Court, Suite 100 | Baltimore, MD 21286
Phone: (888) 981-8378 | Fax: (410) 415-1951 | customerservice@cdlaboratories.com
*A subsidiary of CD Diagnostics, a division of Zimmer Biomet*

CD Laboratories®

*Note: All testing at CD Laboratories is intended for synovial fluid obtained from an intraarticular joint space. All other specimens will be rejected at CD Laboratories.*

## Synovasure® Comprehensive PJI Test Panel with SynTuition®

The Synovasure® Comprehensive PJI Test Panel is intended as an aid in diagnosing periprosthetic joint infection (PJI) through a combination of proprietary and standard of care (SoC) synovial fluid tests for adult patients experiencing joint pain and/or inflammation following a total joint arthroplasty. The panel includes the following tests:

- Synovasure® Alpha Defensin ELISA
- Synovial Fluid C-Reactive Protein (CRP)
- WBC Count with Differential and RBC count
- Specimen Integrity (A280)

The SynTuition® Score is generated utilizing a validated, machine-learning algorithm comprised of the test results included in the Synovasure® Comprehensive PJI Panel. The SynTuition® Score is presented via a colorimetric scale and numerical score from <1% to >99% to aid in the test result interpretation and diagnosis of PJI.

**Note: RBC count, Specimen Integrity (A280) and Culture (Aerobic and Anaerobic) are tested alongside the Synovasure® Comprehensive PJI Panel but is not included in the SynTuition® Score.**

## Synovasure® Comprehensive NSA Test Panel

The Synovasure® Comprehensive NSA Test Panel is intended as an aid in diagnosing native septic arthritis (NSA) through a combination of proprietary and SoC synovial fluid tests for patients experiencing joint pain and/or inflammation in a native joint. The panel includes the following tests:

- Synovasure® Alpha Defensin for NSA (Includes alpha defensin ELISA and lactate)
- Synovial Fluid Culture (Aerobic and Anaerobic)
- Specimen Integrity (A280)
- WBC Count with Differential and RBC count
- Crystal Analysis

## Specimen Integrity Testing

The accuracy of diagnostic tests such as synovial fluid white blood cell count, neutrophil percentage, and others, can be significantly impacted by the quality of the specimen that is submitted for evaluation. As part of every analysis, specimen integrity tests are performed. Physicians are notified when a suboptimal specimen has been submitted. Our specimen integrity tests assess:

- **Absorbance at 280 nm (A280) –** Specimens that fall outside the normal range for synovial fluid may be caused by dilution via saline lavage or use of contrast agents
- **Red Blood Cell Count –** Specimens are verified as characteristic of synovial fluid, not blood.

| | |
|---|---|
| **Synovasure® Alpha Defensin ELISA** | Alpha defensins are antimicrobial peptides released by activated neutrophils in response to infection. The Synovasure Alpha Defensin (AD) ELISA is a qualitative in vitro test developed to detect human alpha defensins 1-3 in the synovial fluid of a person with a suspected joint infection. This test is covered by U.S. patent 7598080. |
| **Synovasure® Alpha Defensin for NSA** | The Synovasure® Alpha Defensin LDT for NSA consists of assays for synovial fluid alpha defensin ELISA and lactate and has been validated for use as an adjunct to aid in the diagnosis of native septic arthritis. |
| **Synovial Fluid C-Reactive Protein (CRP)** | Synovial fluid CRP has been demonstrated to be comparable to serum CRP for the detection of PJI. A CRP cut-off of 4.45mg/L was validated for use at CD Laboratories. |
| **Synovial Fluid Culture** | Anaerobic and aerobic culture bottles are incubated for up to 7 days. Includes organism identification and antibiotic susceptibility. Shoulder specimen cultures are supplemented to enhance growth and incubated for up to 14 days. |
| **Synovial Fluid WBC Count w/ Differential and RBC Count** | Automated high-performance cell count system with differential and RBC count. Elevated white blood cells (>3000 cells/µL) are confirmed with a manual count. |
| **Crystal Analysis** | An assessment of synovial fluid using polarized light microscopy is performed for the presence of CPPD (calcium pyrophosphate dihydrate) and/or MSU (monosodium urate) crystals. |

### Example Diagnosis Codes *(not all inclusive)*

| Primary Diagnosis Code | Secondary Diagnosis Code |
|---|---|
| M25.551 **(Pain in right hip)** | *secondary diagnosis allowed* |
| M25.552 **(Pain in left hip)** | *secondary diagnosis allowed* |
| M25.561 **(Pain in right knee)** | *secondary diagnosis allowed* |
| M25.562 **(Pain in left knee)** | *secondary diagnosis allowed* |
| *Primary Dx required* | T84.51XD **(Infection and inflammatory RX due to internal right hip prosthesis, subsequent encounter)** |
| *Primary Dx required* | T84.52XD **(Infection and inflammatory RX due to internal left hip prosthesis, subsequent encounter)** |
| *Primary Dx required* | T84.53XS **(Infection and inflammatory RX due to internal right knee prosthesis, sequential encounter)** |
| *Primary Dx required* | T84.54XS **(Infection and inflammatory RX due to internal left knee prosthesis, sequential encounter)** |
| *Primary Dx required* | Z96.641 **(Presence of artificial hip joint, right)** |
| *Primary Dx required* | Z96.642 **(Presence of artificial hip joint, left)** |
| *Primary Dx required* | Z96.651 **(Presence of artificial knee joint, right)** |
| *Primary Dx required* | Z96.652 **(Presence of artificial knee joint, left)** |

**For a complete listing of related diagnosis codes, please refer to the ICD-10 code database**

For customer assistance, contact CD Laboratories Customer Service at 888-981-8378 or email customerservice@CDLaboratories.com

To order more Synovasure® Infection Specimen Transportation kits (00-8888-130-01), contact your local Zimmer Biomet representative or Zimmer Biomet Customer Service at 1-800-348-2759, Option 1